

(d) *Conditions of use*—(1) *Beef and non-lactating dairy cattle*—(i) *Amount*. 2.5 mg per kilogram (/kg) body weight as a single subcutaneous injection in the neck.

(ii) *Indications for use*. For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni*, and *Mycoplasma bovis*. For the control of respiratory disease in cattle at high risk of developing BRD associated with *M. haemolytica*, *P. multocida*, *H. somni*, and *M. bovis*. For the treatment of infectious bovine keratoconjunctivitis associated with *Moraxella bovis*. For the treatment of bovine foot rot (interdigital necrobacillosis) associated with *Fusobacterium necrophorum* and *Porphyromonas levii*.

(iii) *Limitations*. Cattle intended for human consumption must not be slaughtered within 18 days from the last treatment. Do not use in female dairy cattle 20 months of age or older. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Swine*—(i) *Amount*. 2.5 mg/kg body weight as a single intramuscular injection in the neck.

(ii) *Indications for use*. For the treatment of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *P. multocida*, *Bordetella bronchiseptica*, *Haemophilus parasuis*, and *Mycoplasma hyopneumoniae*; and for the control of SRD associated with *A. pleuropneumoniae*, *P. multocida*, and *M. hyopneumoniae* in groups of pigs where SRD has been diagnosed.

(iii) *Limitations*. Swine intended for human consumption must not be slaughtered within 5 days from the last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[70 FR 39918, July 12, 2005, as amended at 71 FR 57416, Sept. 29, 2006; 72 FR 54540, Sept. 26, 2007; 73 FR 6018, Feb. 1, 2008; 73 FR 58872, Oct. 8, 2008; 74 FR 53165, Oct. 16, 2009; 78 FR 63872, Oct. 25, 2013]

§ 522.2640 Tylosin.

(a) *Specifications*. Each milliliter of solution contains 50 or 200 milligrams of tylosin activity (as tylosin base).

(b) *Sponsors*. See sponsor numbers in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(1) No. 000986 for use in paragraphs (d)(1), (2), and (3) of this section.

(2) No. 000010 for use as in paragraphs (d)(1) and (2) of this section.

(c) *Related tolerances*. See § 556.740 of this chapter.

(d) *Conditions of use*—(1) *Beef cattle and nonlactating dairy cattle*—(i) *Amount*. 8 milligrams per pound of body weight once daily.

(ii) *Indications for use*. Treatment of bovine respiratory complex (shipping fever, pneumonia) usually associated with *Pasteurella multocida* and *Arcanobacterium pyogenes*; foot rot (necrotic pododermatitis) and calf diphtheria caused by *Fusobacterium necrophorum* and metritis caused by *Arcanobacterium pyogenes*.

(iii) *Limitations*. Administer intramuscularly for not more than 5 consecutive days. Continue treatment 24 hours after symptoms disappear. Use a 50-milligram-per-milliliter solution for calves weighing less than 200 pounds. Do not inject more than 10 milliliters per site. Do not administer within 21 days of slaughter. This drug product is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(2) *Swine*—(i) *Amount*. 4 milligrams per pound of body weight twice daily.

(ii) *Indications for use*. Treatment of swine arthritis caused by *Mycoplasma hyosynoviae*; swine pneumonia caused by *Pasteurella* spp.; swine erysipelas caused by *Erysipelothrix rhusiopathiae*; swine dysentery associated with *Treponema hyodysenteriae* when followed by appropriate medication in the drinking water and/or feed.

(iii) *Limitations*. Administer intramuscularly for not more than 3 consecutive days. Continue treatment 24 hours after symptoms disappear. Do

not inject more than 5 milliliters per site. Do not administer within 14 days of slaughter. If tylosin medicated drinking water is used as followup treatment for swine dysentery, the animal should thereafter receive feed containing 40 to 100 grams of tylosin per ton for 2 weeks to assure depletion of tissue residues.

(3) *Dogs and cats*—(i) *Amount*. Administer 3 to 5 milligrams per pound of body weight by intramuscular injection at 12- to 24-hour intervals. Use 50 milligram per milliliter solution only.

(ii) *Indications for use*—(a) *Dogs*. Treatment of upper respiratory infections such as bronchitis, tracheobronchitis, tracheitis, laryngitis, tonsillitis, and pneumonia caused by *Staphylococci* spp., hemolytic *Streptococci* spp., and *Pasteurella multocida*.

(b) *Cats*. Treatment of upper respiratory infections when caused by *Staphylococci* spp. and hemolytic *Streptococci* spp. and for feline pneumonitis when caused by tylosin susceptible organisms.

(iii) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[46 FR 48643, Oct. 2, 1981, as amended at 47 FR 9398, Mar. 5, 1982; 50 FR 49841, Dec. 5, 1985; 50 FR 50292, Dec. 10, 1985; 53 FR 40728, Oct. 18, 1988; 59 FR 14365, Mar. 28, 1994; 62 FR 35077, June 30, 1997; 68 FR 24879, May 9, 2003; 70 FR 16935, Apr. 4, 2005. Redesignated and amended at 74 FR 11644, Mar. 19, 2009; 79 FR 16198, Mar. 25, 2014]

§ 522.2662 Xylazine.

(a) *Specifications*. Each milliliter (mL) of solution contains xylazine hydrochloride equivalent to:

- (1) 20 milligrams (mg) xylazine.
- (2) 100 mg xylazine.
- (3) 300 mg xylazine.

(b) *Sponsors*. See sponsors in § 510.600(c) of this chapter for uses as in paragraph (d) of this section.

(1) No. 054628 for use of product described in paragraph (a)(2) of this section as in paragraph (d)(2) of this section.

(2) No. 000010 for use of product described in paragraph (a)(2) of this section as in paragraphs (d)(2), (d)(3)(i), (d)(3)(ii)(A), and (d)(3)(iii) of this section.

(3) Nos. 000859 and 061651 for use of product described in paragraph (a)(1) of this section as in paragraph (d)(1); and product described in paragraph (a)(2) of this section as in paragraphs (d)(2), (d)(3)(i), (d)(3)(ii)(A), and (d)(3)(iii) of this section.

(4) No. 061690 for use of product described in paragraph (a)(1) of this section as in paragraph (d)(1) of this section; product described in paragraph (a)(2) of this section as in paragraphs (d)(2), (d)(3)(i), (d)(3)(ii)(A), and (d)(3)(iii) of this section; and product described in paragraph (a)(3) of this section as in paragraphs (d)(3)(i), (d)(3)(ii)(B), and (d)(3)(iii) of this section.

(c) *Special considerations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use*—(1) *Dogs and cats*—(i) *Amount*. 0.5 mg/pound (lb) intravenously or 1.0 mg/lb subcutaneously.

(ii) *Indications for use*. To produce sedation, as an analgesic, and as a preanesthetic to local or general anesthesia.

(2) *Horses*—(i) *Amount*. 0.5 mg/lb intravenously or 1.0 mg/lb intramuscularly.

(ii) *Indications for use*. To produce sedation, as an analgesic, and as a preanesthetic to local or general anesthesia.

(iii) *Limitations*. Do not use in horses intended for human consumption.

(3) *Elk and deer*—(i) *Amount*. Administer intramuscularly, by hand syringe, or by syringe dart, in the heavy muscles of the croup or shoulder as follows:

(A) Elk (*Cervus canadensis*): 0.25 to 0.5 mg/lb.

(B) Mule deer (*Odocoileus hemionus*), sika deer (*Cervus nippon*), and white-tailed deer (*Odocoileus virginianus*): 1 to 2 mg/lb.

(C) Fallow deer (*Dama dama*): 2 to 4 mg/lb.

(ii) *Indications for use*. (A) To produce sedation, as an analgesic, and as a preanesthetic to local anesthesia.

(B) To produce sedation, accompanied by a shorter period of analgesia. May be used to calm and facilitate handling of fractious animals for diagnostic procedures, for minor surgical procedures, for therapeutic medication for sedation and relief of pain following